

## **National Children's Study Vanguard Center Transition Questions and Answers**

*The contracts for the National Children's Study Vanguard Study Centers will soon expire. All of the contracts were initiated for a five-year period with a one-year extension. Before the current contracts expire, however, the federal government will announce opportunities for new contracts. All current contractors will be eligible to compete for the new contracts in a full and open competition. This procedure is standard for nearly all government contracts. Below are a series of questions and answers that provide more information about this process.*

*Please refer to the [National Children's Study Glossary](#) for definitions of Study and contract terms used in the Q&A.*

### **What are the National Children's Study Vanguard Centers?**

The Vanguard Centers are academic institutions, retained under a contract from the federal government, to collect data for the Vanguard, or pilot, phase of the National Children's Study. The Vanguard Study is a small scale study being conducted in advance of the larger, Main National Children's Study. The Vanguard Study will continue for 21 years. The purpose of the Vanguard Study is to evaluate the feasibility, acceptability, and costs of the methods that will be used to carry out the Main Study. The Vanguard Study began in early 2009 at 2 locations, and then expanded over the course of 2009 to a total of 7 locations. In 2010, an additional 30 locations were added for a total of 37. In 2011, 3 more locations were added for a total of 40.

### **How are the Vanguard Centers funded?**

The National Children's Study Centers are funded by contracts. The federal government awards contracts to private entities who have proven their ability to carry out participant recruitment, data and sample collection, and other tasks of the Study. These contracts are awarded for a predetermined interval of time, known as a "period of performance." If additional work is required at the end of a period of performance, a new contract must be competed and awarded. The periods of performance for the contracts awarded to the original 7 Vanguard Centers will begin to expire within the next few months, and the contracts for all the remaining 33 Vanguard locations will expire over the course of the next 18 months.

### **Can the National Children's Study automatically renew the contracts when they expire?**

No. The needs of the Study have changed since the contracts were first awarded. By the time the current contracts expire, all of the participants for the Vanguard Study will have been enrolled and new activities will begin. For this reason, new contracts are needed to define the work needed to meet the Study's evolving needs. Per the original contracts, it is anticipated that the federal government will award new contracts every 5 years, roughly twice a decade.

### **Will the new contracts be awarded immediately after the previous contracts expire?**

The current plan is to identify the new contractors before the current contracts expire. The current contractor and the new contractor will be expected to work together to ensure an orderly transition so that the Study is not interrupted. However, the new contracts will not be ready before the contracts for the initial 7 Vanguard Centers expire. An interim contractor will work with the initial 7 locations until new long-term contracts are awarded. Because the new contracts will include new tasks, a transition process is needed, even for current contractors who are successful in the competition for the new contract.

**Will Main Study locations be involved in this transition process?**

The larger Main Study, anticipated to enroll about 100,000 children from across the United States, has not yet begun and so it will not be involved in the transition process. The launch date of the Main Study has not been determined, but it currently is expected to begin sometime in 2013.

**Have there been any changes in the plans for the Main Study?**

Original plans called for the Main Study to enroll women of childbearing age at the time they became pregnant. The women would be enrolled from previously selected neighborhoods, by Study staff, who would go door to door. However, early results from the Vanguard Study showed that limiting eligibility to selected neighborhoods and relying on door-to-door recruitment would not allow the Study to reach its target of 100,000 children in a reasonable time or at a reasonable cost. National Children's Study researchers then used the Vanguard Study to evaluate alternate recruitment strategies. Results of those evaluations suggested that the most efficient, cost-effective means to recruit Study participants was through health care providers. Such "provider-based" recruitment would also allow the Study to build on information collected through routine health care visits.

**How would the change to provider-based recruitment affect the Study?**

Provider-based recruitment would allow the Study to recruit participants at a faster rate, and for less cost. In addition, access to providers' electronic health records could reduce costs and make it easier for Study staff to keep track of participants if they change addresses. Potential limitations of provider-based recruitment are that some providers may not be interested in participating in the Study, or have sufficient staff or capacity to work with the Study. Similarly, provider-based recruitment may make it more difficult to enroll certain populations, such as individuals who lack health care coverage. These limitations may make it more difficult to acquire certain types of information than would door-to-door recruiting. However, with provider-based recruitment, the Study is still expected to yield a large quantity of scientifically sound information on the environmental and biological factors that contribute to improving the health of children. The National Children's Study leadership is currently engaged in consultation and discussions with many stakeholders to determine how best to implement a new recruitment strategy.

**Would this change interfere with the Study's ability to accurately represent traditionally underserved populations?**

An important objective of the Study is to ensure that underserved and underrepresented populations take part in the Study, including those who do not have access to health care. The National Children's Study is considering strategies to supplement recruitment by health care providers, to include populations that are not covered sufficiently by health care providers and to employ federal, state, and local resources to reach them.